PSY3

RISK OF CARDIOVASCULAR, GASTROINTESTINAL, AND RENAL ADVERSE EVENTS ASSOCIATED WITH DICLOFENAC IMMEDIATE AND EXTENDED RELEASE DRUG PRODUCTS: AN OBSERVATIONAL STUDY USING US CLAIMS DATA
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OBJECTIVES: Safety studies have shown that risks associated with use of non-steroidal anti-inflammatory drugs (NSAIDs) are related to dose and release form; however, there is little US evidence. This study assessed relationships between diclofenac dose and release form on gastrointestinal (GI), cardiovascular (CV), and renal events using US health care claims. METHODS: The MarketScan® Commercial Claims and Encounters database (2008-12) was used. Literature from 1948 on diclofenac was reviewed. GI outcomes were determined using an algorithm and a diagnostic test ordered more than 4 days after exposure to heparin; (B) algorithm A plus presence of ICD-9-CM code 287.4, 287.5, or 289.84; and (C) algorithm A plus presence of ICD-9-CM code 287.4, 287.5, or 289.84. RESULTS: Twenty-eight articles with 2,328 000 study participants were included. Rates were: UGIB: 3.48 (2.25-5.37) for ER and 2.59 (1.55-4.33) for IR; LGIB: 1.58 (1.31-1.91) for ER and 1.37 (1.17-1.50) for IR; and renal failure: 2.25 (1.84-2.76) for ER and 2.10 (1.65-2.63) for IR. CONCLUSIONS: In an analysis of US health care claims, increased risks of certain adverse events were associated with higher doses compared with no current use, with ER compared with IR being the generally most severe with prior history of GI, CV or renal disease. The risk is higher with higher doses compared with no current use, with ER compared with IR being the generally most severe.

PSY6

MAJOR EARLY COMPLICATIONS FOLLOWING BARIATRIC SURGERY: A SYSTEMATIC REVIEW AND META-ANALYSIS
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OBJECTIVES: This systematic review and meta-analysis studied major surgical complications, including pulmonary embolism (PE), myocardial infarction (MI), and leak, resulting from bariatric surgery procedures, using recently published data and appropriate meta-analysis techniques. METHODS: Surgeries considered were Roux-en-Y gastric bypass (RYGB), adjustable gastric banding (AGB), and sleeve gastrectomy (SG). Embase, PubMed, and Cochrane Library databases between 2003 and September 2014 were performed. Articles were screened for exclusion and inclusion criteria before data extraction. Quality of evidence was assessed and each article was rated for quality. Post-surgery complication selective loss of fat and were metabolic abnormalities. Based on patient accounts, synthesized by Bayesian random-effects meta-analyses. In cases where randomized controlled trials (RCTs) and observational studies (OBs) were available, RCTs and OBs were analyzed separately. RESULTS: Our study included 61 articles (60 OBs, 1 RCT) and 108,396 patients with a mean age of 44.3 years and mean pre-surgery body mass index (BMI) of 46.5 kg/m2. Only one article recorded a leak following RYGB at ≥30 days, reporting 2 in 218 patients. The ≤30 day mean rate of complications and the 95% credible intervals (in brackets) for OBs are presented. The leak rate for RYGB was 0.91% [0.56%, 1.35%] and for SG was 0.72% [0.21%, 2.54%]. The MI rate for RYGB was 0.66% [0.02%, 1.15%] and for AGB 1.05% [0.65%, 1.68%]. Incidence of PE for all procedures was 0.35% [0.14%, 0.74%], with AGB having the lowest rate (0.11%), followed by SG (0.54%) and RYGB (0.69%). CONCLUSIONS: This study suggests that the risk of PE, MI, and leak following bariatric surgery is low. However, these are serious, life-threatening adverse events with non-negligible coincidence whose risk should be effectively communicated to patients when surgical treatment is considered.

PSY7

ESTIMATING QUALITY OF LIFE OF PATIENTS WITH LIPODYSTROPHY
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OBJECTIVES: Lipodystrophy syndromes (LD-S) are rare syndromes characterized by fat redistribution and associated metabolic abnormalities. Based on patient accounts synthesized by Bayesian random-effects meta-analyses. In cases where randomized controlled trials (RCTs) and observational studies (OBs) were available, RCTs and OBs were analyzed separately. RESULTS: Our study included 61 articles (60 OBs, 1 RCT) and 108,396 patients with a mean age of 44.3 years and mean pre-surgery body mass index (BMI) of 46.5 kg/m2. Only one article recorded a leak following RYGB at ≥30 days, reporting 2 in 218 patients. The ≤30 day mean rate of complications and the 95% credible intervals (in brackets) for OBs are presented. The leak rate for RYGB was 0.91% [0.56%, 1.35%] and for SG was 0.72% [0.21%, 2.54%]. The MI rate for RYGB was 0.66% [0.02%, 1.15%] and for AGB 1.05% [0.65%, 1.68%]. Incidence of PE for all procedures was 0.35% [0.14%, 0.74%], with AGB having the lowest rate (0.11%), followed by SG (0.54%) and RYGB (0.69%). CONCLUSIONS: This study suggests that the risk of PE, MI, and leak following bariatric surgery is low. However, these are serious, life-threatening adverse events with non-negligible coincidence whose risk should be effectively communicated to patients when surgical treatment is considered.

PSY5

THE VALIDITY OF ALGORITHMS FOR IDENTIFYING SUSPECTED AND CONFIRMED HEPARIN-INDUCED THROMBOCYTOPENIA
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OBJECTIVES: The aim of this study was to develop and compare three algorithms for identifying heparin-induced thrombocytopenia (HIT) using gold standard measures of clinically suspected and actual HIT. METHODS: We identified 45,096 individuals exposed to heparin from 2006 to 2011 in an unlinked academic medical center. Three algorithms were examined: (A) initiation of direct thrombin inhibitor (DTI) treatment and a diagnostic test ordered more than 4 days after exposure to heparin; (B) algorithm A plus NOAC code + 1.4; and (C) algorithm A plus presence of ICD-9-CM code 289.84. The data were collected from medical and billing records for patients (n=39) identified by algorithm A and a random sample (n×0.21) from a non-heparinized sample (n=112). Results: Twenty-eight articles with 2,328 000 study participants were included. Rates were: UGIB: 3.48 (2.25-5.37) for ER and 2.59 (1.55-4.33) for IR; LGIB: 1.58 (1.31-1.91) for ER and 1.37 (1.17-1.50) for IR; and renal failure: 2.25 (1.84-2.76) for ER and 2.10 (1.65-2.63) for IR. CONCLUSIONS: Absent timely and comprehensive conduct of the LDOS pilot study, the safety signal may have gone unnoticed for years. Prospectively-monitored phase IV studies could enhance detection of rare serious adverse events of novel medicines, including biologicals.

PSY3

COMPARISON OF DISEASE STATUS AND OUTCOMES OF PATIENTS WITH ANKYLOSING Spondylitis (AS) RECEIVING ADALIMUMAB OR ETANERCEPT MONOTHERAPY IN THE UNITED STATES (US)
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OBJECTIVES: To compare the disease status and outcomes of patients with AS treated with adalimumab (ADA) and etanercept (ETA) in the US. METHODS: A medical chart-review of AS patients was conducted to collect de-identified data for those recently treated with a biologic as part of usual care. Physicians (rheumatologists) were screened for duration of practice (3-30 years) and patient volume ≥5. Randomized patient recruitment with site identity kept to be geographically representative. Eligible patient chart (≥3) were randomly selected from a sample of patients visiting each center/practice during the screening period. Physicians abstracted patient diagnosis, treatment, patterns/dynamics and patient symptomatology/disease status outcomes. Patients on adalimumab/